Office Action Summary	Application No.	Applicant(s)	
	10/771,620	GRAFF ET AL.	
	Examiner	Art Unit	
	PETER J. REDDIG	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,8,9,66-69,71 and 72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,8,9,66-69,71 and 72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/16/2004*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20080305* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment received March 5, 2008 in response to the Office Action of July 10, 2007 has been received and is entered.

2. Upon review and reconsideration, the finality of the previous action will be vacated and prosecution of application 10/771,620 is reopened.

3. Claims 1, 3, 8, and 9 have been amended, claims 2, 4-7, 10-65 have been cancelled, and new claims 66-69, 71, and 72 have been added.

4. Claims 1, 3, 8, 9, 66-69, 71, and 72 are pending and under consideration.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 3, 8, and 9 remain rejected and claims 66-69, 71, and 72 are rejected under 35 U.S.C. 112, first paragraph, for the reasons previously set forth in section 5, pages 4-6 of the Office Action of July 10, 2007.

Applicants argue that the claims are in condition for allowance.

Applicants arguments have been considered, but have not been found persuasive upon reconsideration as the claims are not limited to detecting SEQ ID NO: 3 or SEQ ID NO: 4 or the full-length complement of either as the alternative language of claim 1 still reads on the variants encompassed by FLJ20174. Thus, the claims remain rejected for the reasons previously set forth.

It is noted that amendment of the claims to assaying the level of FLJ20174 nucleic acid selected from the group consisting of SEQ ID NO: 3 or the full length complement thereof or SEQ ID NO: 4 complement thereof or the full length or removal of the reference to FLJ20174 would obviate this rejection.

6. Claims 1, 3, 8, and 9 remain rejected and claims 66-69, 71, and 72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons previously set forth in section 6, pages 6-7 of the Office Action of July 10, 2007.

Applicants argue that the claims are in condition for allowance.

Applicants arguments have been considered, but have not been found persuasive upon reconsideration as the claims are not limited to detecting SEQ ID NO: 3 or SEQ ID NO: 4 or the full-length complement of either as the alternative language of claim 1 still reads on the variants encompassed by FLJ20174. Thus, the claims remain rejected for the reasons previously set forth.

It is noted that amendment of the claims to assaying the level of FLJ20174 nucleic acid selected from the group consisting of SEQ ID NO: 3 or the full length complement thereof or SEQ ID NO: 4 complement thereof or the full length or removal of the reference to FLJ20174 would obviate this rejection.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 71 and 72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 71 recites the limitation "the probe" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 3, 9, 66-69, 71, and 72 are rejected under 35 U.S.C. 102(e) as being anticipated by Tan et al (US Patent App. Publication 2005/0170351 A1, Feb. 20, 2003) as evidenced by Appendix 1 and Affymetrix (GeneChip® Data Sheet Human Genome Arrays, 2003, p. 1-4).

The claims are drawn to:

1. A method of screening for breast cancer in a subject, the method comprising obtaining a sample containing breast cells from the subject, assaying the level of FLJ20174 nucleic acid, SEQ ID NO:3 or SEQ ID NO:4 or the full length complement of either thereof, comparing the level of FLJ20174 nucleic acid, SEQ ID NO:3 or SEQ ID NO:4 or the full length complement of either thereof, in the sample from the subject with the level of FLJ20174 nucleic acid, SEQ ID NO:3 or SEQ ID NO:4 or the full length

complement of either thereof, in one or more control samples from one or more non-cancerous breast tissues, wherein an increase of at least two-fold in the level of FLJ20174, SEQ ID NO:3 or SEQ ID NO:4 or the full length complement of either thereof, in the subject sample compared to the control samples is indicative of breast cancer in the subject and wherein assaying the level comprises an amplification step.

3. The method of claim 1, wherein the one or more control breast tissue samples from a non-cancerous breast tissue are also from the subject.

9. The method of claim 1, wherein the level of FLJ20174, SEQ ID NO:3 or SEQ ID NO:4 or the full length complement thereof is determined by assaying the sample with a probe or primer consisting of l0, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30 or more contiguous nucleotides of SEQ ID NO:3 or SEQ ID NO:4, or the full length complement thereof.

66. The method of claim 1, wherein the step of assaying comprises a polymerase chain reaction step.

67. The method of claim 1, wherein the step of assaying comprises a reverse transcriptase polymerase chain reaction step.

68. The method of claim 1, wherein the step of assaying comprises a DNA to DNA hybridization step.

69. The method of claim 1, wherein the step of assaying comprises a DNA to RNA hybridization step.

71. The method of claim 1, wherein the probe is affixed to a solid support.

72. The method of claim 71, wherein the solid support is a membrane, a microtiter plate, or a polystyrene bead.

Tan et al. teach the identification of FLJ20174 nucleic acid by microarray analysis using Affymetrix U133A Genechips of breast tumors samples as a gene expressed in ER negative type 2 tumors, where its expression is changed at least two fold compared to other samples including normal samples, see para. 0198-0224 and Table ER-subtype II. Tan et al. teach that all tumor and normal tissues were simultaneously harvested during surgical excision of the tumor, see 0124. Tan et al. teach that the RNA used for hybridization to the cDNA microarrays was generated from RNA of the samples after a single linear amplification step, see 0126. Tan et al. teach that PCR can be used to amplify mRNA with the prior conversion of the RNA to cDNA, which is reverse transcription, for the PCR amplification, which is well known in the art to comprise DNA to DNA hybridization, for detection of the polynucleotides of the invention, see para.0030, 0035, and 0051-0055. Tan et al. teach detection of the nucleic acids with cDNA probes, see para. 0051 and 0052. Tan et al. teach using probes affixed to solid supports, such as membranes and beads for detecting nucleic acids, see para. 0055-0060.

Given that Tan et al. teach using cDNAs for detecting nucleotides of the invention and FLJ20174 is a cDNA identical to SEQ ID NO: 3 (see Appendix 1), Tan et al. teach a probe that is more than 30 contiguous nucleotides of SEQ ID NO: 3.

Additionally, it is noted that the Affymetrix U133A gene chips used by Tan et al. contain 25-mer oligonucleotide arrays complementary to the polynucleotides of the genes being screened, Affymetrix (GeneChip® Data Sheet Human Genome Arrays, 2003, p. 2 and 3). Although the Tan et al. reference does not specifically state that the probes of the Affymetrix

U133A gene chips contained a probe or primer consisting of l0, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30 or more contiguous nucleotides of SEQ ID NO:3 or SEQ ID NO:4, given that FLJ20174 was detected using the Affymetrix U133A gene chips, which contain 25-mer oligonucleotide arrays complementary to the sequences being screened, the claimed product appears to be the same as the prior art product, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product in the method of claim 9. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product in the method of claim 9 is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA).

It is noted that a wherein clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited, MPEP 2111.04. Given that the method of the prior art comprises the same method steps as claimed in the instant invention, obtaining a sample containing breast cells from the subject, assaying the level of FLJ20174 nucleic acid, SEQ ID NO:3 or SEQ ID NO:4 or the full length complement of either thereof, comparing the level of FLJ20174 nucleic acid, SEQ ID NO:3 or SEQ ID NO:4 or the full length complement of either thereof, in the sample from the subject with the level of FLJ20174 nucleic acid, SEQ ID NO:3 or SEQ ID NO:4 or the full length complement of either thereof, in one or more control samples from one or more non-cancerous breast tissues and comprising an amplification step, the claimed method is anticipated because the method will inherently be a method of screening for breast cancer, wherein an increase of at least two-fold in the level of

FLJ20174, SEQ ID NO:3 or SEQ ID NO:4 or the full length complement of either thereof, in the subject sample compared to the control samples is indicative of breast cancer in the subject. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993). Although the reference does not specifically state that an increase of at least two-fold in the level of FLJ20174, SEQ ID NO: 3 or SEQ ID NO: 4 or the full length complement of either thereof, in the subject sample compared to the control samples is indicative of breast cancer in the subject, the claimed method appears to be the same as the prior art method, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the method of the prior art does not possess the same material, structural and functional characteristics of the claimed method. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed method is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tan et al (US Patent App. Publication 2005/0170351 A1, Feb. 20, 2003) as applied to claims 1, 3, 9, and 66-69, 71, and 72 above, in view of Hung et al.(US Pat. No. 6,638, 727, January 26, 1999).

Claim 8 is drawn to the method of claim 1, wherein the subject sample comprises nipple aspirate or ductal fluid obtained from the subject.

Tan et al. teach as set forth above, but do not teach nipple aspirate or ductal fluid obtained from the subject.

Hung et al teach that nipple aspirate fluid is a promising non-invasive method to identify cellular markers of breast cancer risk, see Col 2, line 60 to Col. 3, line 5. Hung et al teach using ductal fluid by nipple aspiration for the identification of the breast cancer cells, see col. 3 and 4.

It would be *prime facie* obvious to one of skill in the art at the time the invention was made to use nipple aspirate or ductal fluid from the subject as the sample to assay the level of FLJ20174 nucleic acid because these are typical samples used in the art to screen for breast

cancer as taught by Hung et al. One of skill in the art would have been motivated with a reasonable expectation of success to use these types of samples because they were normally used in the art for breast cancer detection.

10. No claims allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to PETER J. REDDIG whose telephone number is (571)272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Helms Larry can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Peter J Reddig/
Examiner, Art Unit 1642
/P. J. R./

/Karen A Canella/
Primary Examiner, Art Unit 1643

Appendix 1

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AK000181
LOCUS       AK000181                4669 bp    mRNA    linear   PRI 12-SEP-2006
DEFINITION  Homo sapiens cDNA FLJ20174 fis, clone COL09863.
ACCESSION   AK000181
VERSION     AK000181.1  GI:7020098
KEYWORDS    FLI_CDNA; oligo capping; fis (full insert sequence).
SOURCE      Homo sapiens (human)
  ORGANISM  Homo sapiens
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            Mammalia; Eutheria; Euarchontoglires; Primates; Haplorrhini;
            Catarrhini; Hominidae; Homo.
REFERENCE   1
  AUTHORS   Kawabata,A., Hikiji,T., Kobatake,N., Inagaki,H., Ikema,Y.,
            Okamoto,S., Okitani,R., Ota,T., Suzuki,Y., Obayashi,M., Nishi,T.,
            Shibahara,T., Tanaka,T., Nakamura,Y., Isogai,T. and Sugano,S.
  TITLE     NEDO human cDNA sequencing project
  JOURNAL   Unpublished
REFERENCE   2  (bases 1 to 4669)
  AUTHORS   Sugano,S., Suzuki,Y., Ota,T., Obayashi,M., Nishi,T., Isogai,T.,
            Shibahara,T., Tanaka,T. and Nakamura,Y.
  TITLE     Direct Submission
  JOURNAL   Submitted (15-FEB-2000) Sumio Sugano, Institute of Medical Science,
            University of Tokyo, Deptment of Virology; Shirokane-dai, 4-6-1,
            Minato-ku, Tokyo 108-8639, Japan (E-mail:flcdna@ims.u-tokyo.ac.jp,
            Tel:81-3-5449-5286, Fax:81-3-5449-5416)
COMMENT     NEDO human cDNA sequencing project supported by Ministry of
            International Trade and Industry of Japan; cDNA full insert
            sequencing: Research Association for Biotechnology; cDNA library
            construction, 5'- & 3'-end one pass sequencing: Departent of
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            University of Tokyo (partly supported by Science and Technology
            Agency).
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ORIGIN

  Query Match             100.0%;  Score 4669;  DB 5;  Length 4669;
  Best Local Similarity   100.0%;  Pred. No. 0;
  Matches 4669;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 TTTTTATTATTGCTGTTATTGAGGTTGAGGGAGAAGAGATCGGTCTAAATTCTGGCTGGG 60
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ACCESSION   AK000181
VERSION     AK000181.1  GI:7020098
KEYWORDS    oligo capping; fis (full insert sequence).
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  ORGANISM  Homo sapiens
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REFERENCE   1  (sites)
  AUTHORS   Kawabata,A., Hikiji,T., Kobatake,N., Inagaki,H., Ikema,Y.,
            Okamoto,S., Okitani,R., Ota,T., Suzuki,Y., Obayashi,M., Nishi,T.,
            Shibahara,T., Tanaka,T., Nakamura,Y., Isogai,T. and Sugano,S.
  TITLE     NEDO human cDNA sequencing project
  JOURNAL   Unpublished (2000)
REFERENCE   2  (bases 1 to 4669)
  AUTHORS   Sugano,S., Suzuki,Y., Ota,T., Obayashi,M., Nishi,T., Isogai,T.,
            Shibahara,T., Tanaka,T. and Nakamura,Y.
  TITLE     Direct Submission
  JOURNAL   Submitted (15-FEB-2000) Sumio Sugano, Institute of Medical
Science,
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            University of Tokyo, Deptment of Virology; Shirokane-dai, 4-6-1,
            Minato-ku, Tokyo 108-8639, Japan (E-mail:cdna1@ims.u-tokyo.ac.jp,
            Tel:81-3-5449-5286, Fax:81-3-5449-5416)
COMMENT     NEDO human cDNA sequencing project supported by Ministry of
            International Trade and Industry of Japan; cDNA full insert
            sequencing: Research Association for Biotechnology; cDNA library
            construction, 5'- & 3'-end one pass sequencing: Departent of
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